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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,665	06/23/2000	Caroline Barry	G-067US03REG	8150
23557	7590	02/15/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,665

Applicant(s)

BARRY ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-132 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-132 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Upon reconsideration of the broad scope of sequences (comprising contiguous span of 6 and 10 amino acid fragments) of the claims the finality of the previous office action is withdrawn and the prosecution is reopened herein.
2. Applicants' response to the office action and amendment filed on December 12, 2004 has been considered and entered.
3. New claims 128-132 are added. Claims 1-78 are cancelled. Claims 80, 85-86, 99, 121, 126 are amended. Claims 79-132 are pending.
4. The instant application filed on June 23, 2000 claims benefit of US provisional application 60/141,323 filed on 6/25/1999 and 60/176,880 filed on 1/18/2000.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79-132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claim 79 is drawn to an isolated polypeptide comprising at least 10 contiguous amino acids shown as positions 1 to 1629 of SEQ ID NO. 5. The instant claim 85 is

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drawn to a variant polypeptides comprising at least 6 contiguous amino acids of SEQ ID NO. 5. The instant claim 86 is drawn to a composition of isolated polypeptide comprising at least 10 contiguous amino acids of said polypeptide (said 10 contiguous amino acids comprising positions 1-200, 210-400, 401-600, 601-800, 801-1000, 1001-1200, 1201-1400, 1401-1629 of SEQ ID NO. 5). Claims are further drawn to polypeptide fragments comprising at least 20 contiguous amino acids, at least 40 contiguous amino acids, variants and an antibody directed to said fragments. The specification fails to provide structural limitations of said isolated polypeptide fragments comprising at least 10 amino acids. Further the specification fails to provide any information regarding the biological activity of said fragments. The large genus of fragments is represented in the specification by the broad sequence SEQ ID NO. 5. Thus, applicants have expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) With regard to the isolated polypeptide fragments having at least 10 contiguous amino acids, and fragments comprising at least 6 contiguous amino acids with specific amino acid substations, it is insufficient to demonstrate identity of regulatory activity in said fragment(s) where no structural information regarding where in the fragment the activity resides. Further no information is given regarding a

methodology to determine such common elements or attributes. Further, there is no description of fragments or variants.

With regard to the written description, all of the claims drawn to a large number of polypeptide fragments encompass different structural limitations, for which, no structural limitation is provided in the specification. It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In this application at the time of filing, there is no record or description, which would demonstrate conception or written description of any biological activity of isolated polypeptide fragments comprising at least 10 contiguous amino acids or variants comprising at least 6 contiguous amino acids.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 80, 82, 83, 86, 96, 97, 109-111, 121, 123-125, 127, 129-130, 132, are rejected under 35 U.S.C. 102(b) as being anticipated by Bowcock et al. (WO 98/12327).

With regard to claim 80 (step b), 82, 86 (Step j), 96, 127, 129-130, Bowcock et al. teach an isolated or purified polypeptide comprising at least a contiguous span of at least 6 amino acids or at least 10 amino acids of the claimed SEQ ID NO. 5, wherein fragment comprises valine at an amino acid position corresponding to position 1854 of SEQ ID No. 5 (see sequence alignment with position 1854 of SEQ ID NO. 5);

With regard to claim 80 (step c), 83, 86 (step k), 97, Bowcock et al. also teach an isolated or purified polypeptide comprising at least a contiguous span of at least 6 amino acids of the claimed SEQ ID NO. 5, wherein fragment comprises asparagines at an amino acid position corresponding to position 1967 of SEQ ID No. 5 (see sequence alignment with position 1967 of SEQ ID NO. 5);

With regard to claim 80 (step d), 84, 86 (step l), 98, Bowcock et al. also teach an isolated or purified polypeptide comprising at least a contiguous span of at least 6 amino acids of the claimed SEQ ID NO. 5, wherein fragment comprises glutamic acid at an amino acid position corresponding to position 2017 of SEQ ID No. 5 (see sequence alignment with position 2017 of SEQ ID NO. 5);

With regard to claims 109-111, 132, Bowcock et al. teach a method of making said polypeptide using recombinant vectors comprising prokaryotic and eukaryotic vectors (see page 125, line 25-32, page 127, line 5-17);

With regard to claims 121, 123-125, Bowcock et al. teach an isolated purified antibody production (see page 139, line 7-15). Thus the disclosure of Bowcock et al. meets the limitations in the instant claims.

C. Claims 80 (step a), 81, 86 (step l), 95, 121, 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Homburger et al. (USPN. 6,703,491).

Homburger et al. teach an isolated polypeptide with regard to claims 80-81, 86, 95, comprising at least a contiguous span of at least 6 amino acids of the claimed SEQ ID NO. 5, wherein fragment comprises asparagines at an amino acid position corresponding to position 1694 of SEQ ID No. 5 (see sequence alignment with position 1694 of SEQ ID NO. 5);

With regard to claims 121-122, Homburger et al. also teach an antibody directed to said polypeptide (see col. 31, line 41-65). Thus the disclosure of Homburger et al. meets the limitations in the instant claims.

Conclusion


No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

